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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,436	VERNET ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,29,32 and 44-48* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 7, mailed on September 3, 2002), Applicants filed an election (Paper No. 9) and amendment 2002 (Paper No. 10) received on November 8. Said amendment cancelled Claims 5-28, 30, 31, and 33-43 and added new Claims 44-48. Thus, Claims 1-4, 29, 32, and 44-48 are pending in the instant Office action.

Election

2. Applicants' election of Group 7, Claims 1-4, 29, and 32 as related to SEQ ID NO: 14, in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Newly added Claims 44-48 are grouped with SuperGroup B, Group 14 and will not be examined herein. While they depend from polypeptide claims, encoding DNA must be searched to examine these claims. Thus, they have been grouped with SuperGroup B.

Claims 1-4, 29, 32, and 44-48 are pending. Claims 44-48 are withdrawn from further consideration as non-elected inventions. Claims 1-4, 29, and 32 will be examined herein.

Priority

3. The instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/182,637 filed on February 15, 2000, 60/237,862 filed on October 4, 2000, and 60/240,316 filed on October 13, 2000 as requested in the declaration and the first lines of the specification.

Information Disclosure Statement

4. The information disclosure statements filed on May 15, 2001 (Paper No. 4) and October 29, 2001 (Paper No. 5) have been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copy. The Examiner notes that the search report cited on Paper No. 5 has been crossed out; it has been considered, but it not printed on the face of the file.

Objections to the Specification

5. The following inconsistencies in Tables with sequences in the specification and require explanation:

a) On pages 9-10, Table 5 is noted in the text as describing a comparison between NOV2 and chromosome 11 (CHR11). However, NOV1 is listed in Table 5 as compared to CHR11. Moreover, SEQ ID NO: 16 is used to describe NOV1 (or NOV2) in Table 5 and NOV1 is described in the text as SEQ ID NO:1, NOV2 as SEQ ID NO:3. Which is correct?
b) On page 10, the NOV3 polypeptide is described as SEQ ID NO: 6, a 617 amino acid polypeptide; however, SEQ ID NO:6 is a 616 amino acid polypeptide in the sequence listing. Which is correct?
c) On pages 12-13, Tables 7 and 8 both have a nucleic acid sequence labeled "CHR Y"; however, the sequences in each case appear wholly different in sequence, from different sources (see text) and with different SEQ ID NOs. Moreover, NOV3 nucleic acid sequence is labeled SEQ ID NO: 18 or SEQ ID NO:20. The text labels NOV3 as SEQ ID NO: 5. Which is correct?
d) On pages 13-15, Tables 9-11 label NOV3 polypeptides as SEQ ID NO: 22, 24, or 27. Which is correct? The text labels NOV3 as SEQ ID NO: 5. Moreover, GLY T polypeptides are labeled as SEQ ID NO: 23, 25, or 26. Which is correct?
e) On page 16, Table 13 labels NOV4 nucleic acid as SEQ ID NO:28 while the text labels it as SEQ ID NO:7, which is correct?
f) On page 17, line 20, NOV5 polypeptide is described as SEQ ID NO: 9; this is an apparent typographical error since SEQ ID NO:9 is the DNA and 10 is the encoding protein.
g) On pages 19-24, in Tables 15-17, numerous occurrences of NOV5 nucleic acid sequences label the sequence with SEQ ID NO: 30, 32, 34, or 36. The text describes NOV5 nucleic acid sequence as SEQ ID NO:9. Nucleic acid sequence PP1201 is labeled as SEQ ID NO:31 or 33. Which are correct?

h) On page 24, in Table 18, NOV5 polypeptide is labeled as SEQ ID NO:38. The text describes NOV5 polypeptide sequence as SEQ ID NO:10. Which are correct?
i) On pages 27-29, in Tables 20-22, NOV6 nucleic acid sequences are labeled as SEQ ID NO:40 or 43. Which is correct? The text described NOV6 nucleic acid sequence as SEQ ID NO:11.
j) On page 33, Table 24, the NOV7 nucleic acid sequence is labeled as SEQ ID NO:45 while the text describes it as SEQ ID NO:13. Which is correct?
k) On pages 33-34, in Tables 25-26, the NOV7 polypeptide is labeled as SEQ ID NO: 47 or 49 while the text describes is as SEQ ID NO:14. Which is correct? Also in these Tables, the GLY T polypeptide is labeled as SEQ ID NO: 48 or 50 while previously on pages 13-15, the BLY T polypeptide is described as SEQ ID NO: 23, 25, or 26. Which is correct?

For the occurrences of the NOVX nucleic acid and polypeptide sequences, the Examiner suggests describing portions of the full-length sequence using original SEQ ID NOs for clarity. The same is true for duplicated portions of sequences disclosed that have homology to NOVX sequences. Correction is required for clarity.

6. The specification is objected to for the following informalities:

a) On page 1, line 32, in the first occurrence of the abbreviation "NOVX", it must be defined.
b) On page 30, line 21, in the description of NOV7, NOV6 is mentioned; this is likely a typographical error.
c) On pages 33-34, the numbering of NOV7 is incorrect.
d) Tables 2-27 must be in Figures, separate from the text of the specification.

Appropriate correction is required.

7. The specification is objected to for being confusing concerning the functions of NOV7 and NOV3. In their respective sections, both are names as N-acetylglucosaminyl transferases; however, in Table 1, only NOV7 is named as such. Clarification is required.

8. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---N-Acetylglucosaminyl Transferase Polypeptides from Human---

9. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests defining "NOVX" and the inclusion of the source species, human, for completeness.

Claim Objections

10. Claims 1-4, 29, and 32 are objected to for a typographical error. In Claim 1, line 3, the word "sequenceof" should be ---sequence of---. Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4, 29, and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, items a and b, the term "mature form" of the noted amino acid sequence is unclear. No processing of the NOV7 polypeptide is described.

The difference between items a and b and items c and d is wholly unclear. Clarification is required.

12. Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "conservative" substitution has numerous meanings in the art and no clear definition in the specification or the claims. Thus, the metes and bounds of the term are wholly unclear. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 4, 29, and 32 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2, specifically items b and d, is drawn to polypeptide sequences that are 85% identical to SEQ ID NO:14 without also limiting the function of the claimed polypeptides. Also Claim 2, specifically item e, is drawn to a fragment of SEQ ID NO:14 (or a sequence 85% identical to SEQ ID NO:14) in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses polypeptides with at least 85% identity with SEQ ID NO:14. Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having N-acetylglucosaminyl transferase function). However, the genus of the instant claims also contains polypeptides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

The instant specification discloses an N-acetylglucosaminyl transferase and fragments thereof. Applicants have fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations (i.e., having N-acetylglucosaminyl transferase function). However, the genus of the instant claims also contains polypeptides within

the sequence fragment limitations, but having different function. Applicants have not fully described a genus that has sequence fragment limitations in the absence of functional limitations.

14. Claims 2 and 3 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Although the genus of allelic variants that are the result of the translation of single nucleotide polymorphisms is discussed in the specification, there is no evidence that any representative species of the genus was in the possession of the inventors at the time of filing. Moreover, the specification, as filed, has not described this sub-genus of polypeptides that are at least 85% identical to SEQ ID NO:14.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification does not disclose any representative species of allelic variants, with or without identifying characteristics. Moreover, the specification does not adequately describe the subgenus of polypeptides that are variants of SEQ ID NO:14 as the result of the translation of SNPs because none are described, either expressly or predictably. Thus, one of skill in the art would be unable to identify members of the claimed genus of Claims 2-3. Therefore, Claims 2-3, as written, fail to satisfy the written description requirement.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 29, and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO9846757 (see PTO-1449). The instant claims are drawn to polypeptides comprising a fragment of SEQ ID NO:14.

WO9846757 teaches a 756 amino acid sequence, SEQ ID NO:10, that from 268-294 is identical to the fragment of SEQ ID NO:14 that is 201-227 (see attached alignment). WO9846757 also teaches therapeutic uses of the disclosed polypeptides including pharmaceutical compositions and kits thereof.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AW177837 (IL3-HT0059-180899-007 HT0059 Homo sapiens cDNA, mRNA sequence created November 16, 1999) in view of Bork *et al.* (From genome sequences to

protein function. Current Opinion in Structural Biology (1994) 4:393-403). The instant claims are drawn to polypeptide fragments and/or related sequences (85% identical) to SEQ ID NO: 14.

GenBank Accession Number AW177837 teaches a 675 bp mRNA whose sequence exactly encodes SEQ ID NO: 14 residues 176-400 (of the full-length 695 sequence). GenBank Accession Number AW177837 does not teach the encoded protein of the EST. Nor does GenBank Accession Number AW177837 teach methods of identifying a full-length gene and producing its protein product.

Bork *et al.* teach the technologies of taking small portions of genes (ESTs) and producing the protein products (see Abstract and page 394, left column). Such technologies require the use of vectors and host cells as claims in Claims 6-8.

It would have been obvious to one of ordinary skill in the art to (1) screen a human cDNA library for the full-length gene of the EST taught by GenBank Accession Number AW177837, (2) comprise a vector containing said full-length gene, and (3) express said full-length gene in a host cell to make the encoded protein because the sequence of GenBank Accession Number AW177837 is taught as an EST and ESTs are expressed sequence tags of full-length proteins being expressed, in this case, in humans. Expressed proteins are useful to the structure and/or function of organisms. One would have been motivated to combine the instant prior art because, while the prediction of protein function from ESTs is becoming more commonplace and predictable, much information must be confirmed and/or learned from assaying the expressed protein product of an EST. One would have had a reasonable expectation of success that the EST taught by GenBank Accession Number AW177837 could identify the full-length gene because said EST is a large portion of the full-length protein. The cloning of

such genes and their expression is also reasonably within the skills of an artisan at the time of the invention.

The Examiner notes that the claims to the exact protein sequence, like in Claim 1 item c, cannot be anticipated or obviated by the instant prior art because portions of the full length sequence, while able to identify the gene encoding the full-length protein claimed, cannot predict the structure of the full-length sequence (*In re* Deuel). Claims drawn solely to the full-length protein sequence would also not be anticipated or obviated by this prior art; however, no such claims are claimed presently since the protein claims contain % identity language.

Other Art of Interest

17. The Examiner is citing the following references to complete the record:

a) WO 02/26950 (Lal *et al.*) discloses SEQ ID NO:14 that is 93% identical to Applicants' SEQ ID NO:14 (see attached alignment).

Conclusion

18. Claims 1-4, 29, and 32 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
January 22, 2003